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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------|---------------------|------------------|
| 10/621,302 | 07/17/2003 | Anders Bendtz Kanstrup | 6197.214-US | 2223 |
| 7590 | 02/18/2004 | | EXAMINER | |
| Reza Green, Esq. Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540 | | | BERCH, MARK L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/621,302 | KANSTRUP ET AL. | |
| | Examiner | Art Unit | |
| | Mark L. Berch | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-54 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09935149.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Klinger.

See rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klinger.

Note the species of Column 2, lines 26-28, the 8-piperazino species, viz 7-[3-[2-(2-hydroxyphenyl)-2-hydroxyethylamino]-propyl]-8-piperazino-theophylline. The reference teaches compounds of Formula II (Column 2, line 58) as intermediates used to prepare this compound. Z can be halogen; intermediates of this type are shown in Table 2, first column when halogen = Cl. This corresponds in the claims to R¹ = ethylene, R² = halogen. Or Z can be amino, seen in Table 3, again, first column. This corresponds to R¹ = ethylene, R² = H, R⁴ = amino. The reference also has a second process, using compounds of Formula IV, column 3, line 12. There are two choices

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given for V. The second is the amino methyl, which is identical to the Z = amino mentioned above. The other choice is V = C(O)H. This corresponds to R¹ = methylene, R² = methyl substituted by R¹¹, where R¹¹ = oxo. It appears that this second process was not used to prepare the compounds of the actual examples. Thus, in order to prepare the species of Column 2, lines 26-28, the 8-piperazino species, it must go through an intermediate, and hence those intermediates are placed in the public domain, since R⁴ can be piperazino (see e.g. Column 1, lines 44-48 or claim 12 of the patent), and thus are anticipated. Alternatively, it would be highly obvious to prepare the intermediates, since that is what the reference teaches you must do to prepare these compounds. As for the rest of the molecule, this corresponds to R⁶ = R⁷ = methyl, R⁹ = R¹⁰ = H, n = 2, m = 1.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as anticipated by Bonnet.

Note the product of Example 1, step E. This corresponds to R3 as C₄-alkyl, substituted by two R12 groups, one of which is OH, and the other of which is aryl.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The third species removed by proviso from claim 1 is not included in the fist place. It has a linkage of $7-(\text{CH}_2)_2 - \text{OC(O)} -$ which isn't permitted.
2. The first choice at page 118, line 11 is impossible; the P has 6 bonds. Should there be 2 protons and not just one? Is there one to many oxygens atoms?
3. Likewise the next term, where the P again has 6 bonds.
4. The last choice at page 118, line 4 is defective. The carbon of attachment has only three bonds. Should the atom of attachment have been a N? Should there be 3 methoxy groups? Should there be a H on the Carbon? For whichever choice is made in points 2-4, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended.
5. The R¹ choices must all be divalent, since the variable is divalent. Thus, e.g. "alkyl" should be "alkylene".
6. At page 117, line 14, "preferably" is improper alternative language because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
7. On page 118, line 17, that should be "together with the C to which they are attached". Likewise page 117, line 13 should say "form with the carbon"
8. The last term at page 118, line 9 is misspelled.
9. On the last line of page 117, line 13 what is the nature of the ring?

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10. The formatting of R5 is inconsistent. For example, page 117 line 4 has R5 but line 5 has R⁵. Applicants must pick one or the other.

Specification

The abstract is objected to as failing to convey what the compounds actually looks like. Suggested is Formula I, along with definitions for n, m, R¹ and R².

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

2/4/04